

lumen we placed a second, shorter stent in the upper part of the first stent. The Edwards Sapien XT valve mounted on the Novaflex delivery system was then deployed. In the dual caval valve approach we implanted a second valve into the vena cava superior (SVC) as described.

Results: From August 2nd, 2012 to now we treated 6 pts (2 f, 4 m; 5 IVC single, 1 IVC and SVC dual valve) with a FU up to 11 mo. Safety: Periprocedural mortality: 0%; technical success: 100%; VARC 30-day safety endpoint: 0%; valve dysfunction: 0%. Clinical results: 5/6 pts improved by at least 1 NYHA class, in 5/6 pts signs of right heart congestion decreased, in 2/2 pts with cardiorenal syndromes and terminal failure renal function improved allowing discontinuation of dialysis. In 6/6 pts hepatic veins diameters decreased (-34%). Right heart parameters: In msCT measurements volumes of the anatomical RV decreased (-14,8%), surprisingly, also volumes of the anatomical RA decreased (-13%). In echo measurements, TAPSE increased from 14,5 to 18,6 cm.

Conclusions: Percutaneous single or dual caval valve implantation with the Edwards Sapien XT for severe TR is feasible and safe. With all due care at this early stage, this approach appears to be a new promising interventional tool to improve right heart hemodynamics and to ameliorate symptoms of right heart failure in advanced stages of heart failure.

TCT-130

Marrow stromal cell based transcatheter aortic valve implantation – experiences in a preclinical animal model

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Background: Transcatheter aortic-valve implantation (TAVI) has rapidly evolved as an effective treatment alternative for aortic-valve disease. The currently utilized bio-prostheses are prone functional degeneration. Autologous, stem cell based, tissue-engineered heart-valves (TEHV) with self-repair capacity have been repeatedly proposed to overcome these limitations. We summarize our initial experience on marrow stromal cell based TAVI in an adult sheep model.

Methods: Tri-leaflet TEHV generated from synthetic-scaffolds were integrated into self-expanding Nitinol stents, seeded with autologous marrow-stromal cells. Thereafter, in a series of animal experiments, TEHV were transapically delivered into the descending aorta (n=3) and the orthotopic aortic-valve position of adult sheep (n=16) using different delivery systems including a generic system and the anatomically-orienting JenaValve transapical TAVI System (JenaValve, Munich/Germany). Follow up was up to two weeks. Positioning and functionality were assessed by angiography and echo before the TEHV underwent post-mortem gross examination and histology. CT scan was used to assess stent positioning.

Results: Transcatheter implantation of TEHV into the descending aorta (n=3) and into the orthotopic aortic-valve position (n=16) was successful in all animals. Fluoroscopy and echo confirmed sufficient positioning at the intended delivery site. All TEHV tolerated the loading-pressure of the systemic-circulation and no acute ruptures or tears occurred. Animals displayed intact and mobile leaflets with an adequate functionality (mean trans-valvular gradient <10mmHg in all animals). Importantly, TEHV orthotopically implanted (n=16) entirely excluded the native aortic leaflets and did not compromise the coronary arteries. Histology was indicative for an early cellular-remodelling.

Conclusions: We demonstrate transcatheter based TEHV implantation into the aorta within a one-step intervention. Our data indicate the feasibility to combine the concept of TEHV and transcatheter delivery representing a key step towards clinical translation. Long-term functionality proven, a cell based TEHV approach may represent a next generation heart-valve therapy concept.

TCT-131

Use Of A Novel Echo-fluoroscopy Overlay System For Percutaneous Mitral Valve Intervention

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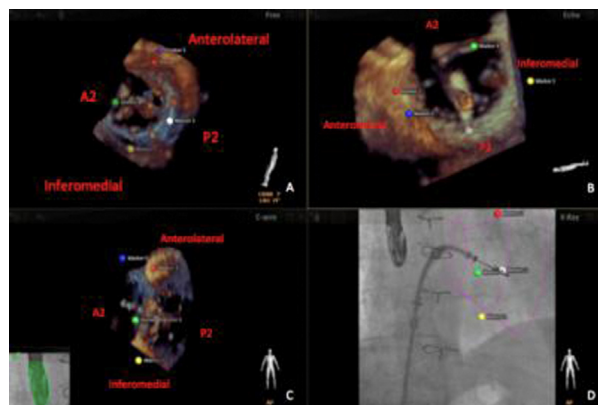
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Background: Percutaneous mitral valve repair requires a close understanding of both fluoroscopy and periprocedural imaging. Real time 3D transesophageal echocardiography is often used for guidance. We report the use of 3D-echocardiography-fluoroscopy fusion for mitral valve repair.

Methods: Patients presenting to our center for mitral valve repair had their procedure performed using an echocardiographic-fluoroscopic overlay system. The EchoNavigator (Philips, Inc) system requires transesophageal echocardiography, which is registered to fluoroscopy based on probe angle and position. Relevant structures can be marked on echocardiography and tracked with fluoroscopy. Procedural characteristics of these patients were collected.

Results: Nine patients at our center underwent percutaneous mitral valve repair with MitraClip (Abbott Vascular, Santa Clara, CA) using a novel 3D-echocardiographic-fluoroscopic overlay technology (EchoNavigator, Philips Inc.). The EchoNavigator system was useful for transseptal puncture, understanding mitral valve anatomy, sheath exchange, clip advancement, and post-deployment visualization.

Conclusions: The use of EchoNavigator echo-fluoroscopy overlay system is feasible and useful in MitraClip intervention.



TCT-132

Prospective, Multicenter Tack Optimized Balloon Angioplasty (TOBA) Study for Femoropopliteal Arteries Using the Tack-IT Endovascular System™

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Background: We evaluated an alternative method to treat post PTA dissection using a novel device, The Tack-IT Endovascular System™, by Intact Vascular, Wayne, PA, indicated for tissue apposition to optimize angioplasty results in peripheral arteries. The Tack is a circumferential, self-expanding Nitinol device 6mm in length. The Tack is designed to provide focal treatment only where needed. The Tack accommodates arterial diameters between 2.5 - 5.5mm and has low outward force onto the arterial wall. Up to 8 Tacks can be used to treat lesions up to 100mm in length.

Methods: One hundred thirty eight subjects were enrolled in the Tack Optimized Balloon Angioplasty (TOBA) study. The lesion length was <100mm. The primary endpoints were Safety and Device Technical Success at 30 days. Safety included major device-related adverse event(s) including device embolization, emergency surgical revascularization, index limb amputation (above the ankle) or clinically-driven TLR at 30 days. Device Technical Success was the ability of the Tack to resolve post-PTA dissection demonstrated that the artery at the Tack(s) location remained patent at the end of the procedure (<30 % residual stenosis). Subjects were followed 1, 6 and 12 months.

Results: FULL STUDY RESULTS WILL BE AVAILABLE BY TCT. Ninety one of the 138 subjects are enrolled. The mean age was 70 with 62% males. The comorbidities included 65% with diabetes, 62% smokers, 73% hypertension and 64% elevated cholesterol. Eighty four (84) subjects had a sub-optimal PTA, 5 optimal PTA and 2 did not meet the I/E criteria. The mean lesion length was 47.5mm and RVD 5.40mm. At 30 days (primary endpoint) there were no major device-related adverse events, emergency surgical revascularizations, no index limb amputations. One (1) clinically-driven TLR (1.2%) reported. One hundred percent (100%) technical success was achieved in all the treated lesions and all (292) Tacks were successfully placed.

Conclusions: The Tack is designed to create tissue apposition with minimal amount of metal and low outward force to allow natural arterial flexibility and low neointimal response. Long term clinical evidence will confirm the clinical benefits of this novel technology.

TCT-133

THE MULTILAYER FLOW MODULATOR STENT FOR THE TREATMENT OF PERIPHERAL AND VISCERAL ANEURYSMS.

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Background: Arterial aneurysms (An) are traditionally treated surgically, but more and more by interventional procedures with a high technical success rate, but some problems are not solved like protection of aneurysm rupture, endoleaks, stent thrombosis, collateral branch thrombosis. We used a new concept of stent, the Multilayer Flow Modulator (MFM*) to treat An. and try to avoid some drawbacks encountered with endografts.

Methods: This MFM* is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest in vitro (theoretical simulation), computerized Fluid dynamics, Molecular Modelization and in vivo tests demonstrated that this MFM* reduces the velocity in the aneurysmal sac up to 90% by modifying the